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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,611	11/30/2001	Min-Yuan Chou	32350-176844	4109

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,611	CHOU ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/18/02*, *4/29/02*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-5 and 9-20 in the Response filed August 8, 2003 is acknowledged. However, the grounds for the traversal are not indicated in the response. In the preliminary amendment filed November 30, 2001, claims 7 and 18 have been amended, and a new claim 21 has been added. Therefore, claims 1-5 and 9-21 are examined. Claims 6-8 of Group II are non-elected inventions, thus withdrawn from consideration.

The requirement is still deemed proper and is therefore made FINAL.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification recites amino acid and nucleotide sequences (e.g., pages 15, 16, 19, 21 and Figs 6A-6C), however, the sequence identifier "SEQ ID NO:" is not indicated for the cited sequence. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing and to identify each sequence with a "SEQ ID NO:". Appropriate correction is required.

3. Figs 7A, 7B, 9A, 9B, 10A and 10B do not show the bands for hybridization product or expression product as indicated in the drawing description. Appropriate correction is required.

Deposit of Biological Materials

4. The Office notes that a deposit of KS(+)/E. Coli DH(hCOLA1) clone, which was deposited on November 14, 2000 with the Culture Collection and Research Center (CCRC), Hsinchu, Taiwan, has been given the accession number 940331 (page 10, lines 16-19 of the specification). Therefore, no 35 U.S.C. 112 paragraph 1 rejection has been entered even though

it is apparent that the claimed deposit material is essential to the claimed invention and the deposit is necessary for an adequate written description and enablement for the claimed invention. Applicant should provide a photocopy of the receipt of the certificate of deposit, and amend the specification to disclose the complete address of the depository.

Claim Objections

5. Claims 1-3 and 17-21 are objected to because of the use "SEQ ID NO.". Use of "SEQ ID NO:" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 17-21 are directed to a nucleic acid comprising at least 500 contiguous nucleotides (claim 17) or at least 20 contiguous nucleotides (claim 19) of SEQ ID NO:5 or a complementary nucleotide sequence thereto; a kit for detecting a disease related to the mutation of SEQ ID NO:5 in a mammal comprising a probe, which comprises a nucleic acid having SEQ ID NO:5 (claim 18) or a nucleotide sequence containing at least 500 contiguous nucleotides of SEQ ID NO:5 (claim 21); or a kit for detecting a disease related to the mutation of SEQ ID NO:5 in a mammal comprising a primer, which comprises a nucleic acid having at least 20 contiguous

nucleotides of SEQ ID NO:5 (claim 20). The specification indicates that the invention provides nucleotide fragments derived from SEQ ID NO:5 as a nucleic acid probe or primer, and a diagnostic kit for detecting the disease related to the mutation of SEQ ID NO:5 in a mammal or human comprising the nucleic acid probe or primer (page 4, line 18-page 5, line 17). However, the specification has not identified any fragment of SEQ ID NO:5 having at least 500 or 20 contiguous nucleotides used as a probe or a primer, nor has demonstrated the mutation of SEQ ID NO:5 is related to the cited diseases. Without guidance on identities of the fragments of SEQ ID NO:5 having at least 500 or 20 contiguous nucleotides and of mutation of SEQ ID NO:5, and the correlation of structure to function/activity, one skilled in the art would not know how to use the fragments of SEQ ID NO:5. The lack of representative examples and teachings on the fragments of SEQ ID NO:5 containing at least 500 or 20 contiguous nucleotides and the mutation of SEQ ID NO:5 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5 and 9-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1-5, 9-16 and 18 are indefinite because of the use of the term "An isolated nucleic acid and the degenerate sequences thereof,....., comprising the nucleotide sequence set forth in

SEQ ID NO. 5". The term "An isolated nucleic acid and the degenerate sequences thereof,....., comprising the nucleotide sequence set forth in SEQ ID NO. 5" renders the claim indefinite, it is not clear how a nucleic acid and its degenerate sequences comprise the same nucleotide sequence "SEQ ID NO:5". Claims 2-5, 9-16 and 18 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

10. Claims 2 and 3 are indefinite because claim 2 has a broader scope than the independent claim, claim 1. Claim 2 is directed to a nucleic acid encoding the protein having SEQ ID NO:1, which includes SEQ ID NO:5 and its degenerate sequences, while claim 1 is directed to a nucleic acid comprising SEQ ID NO:5. Claim 3 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

11. Claims 4 and 5 are indefinite because of the use of the term "comprising DNA and RNA" or "DNA comprises cDNA and genomic DNA". The term "comprising DNA and RNA" or "DNA comprises cDNA and genomic DNA" renders the claim indefinite, it is not clear how a nucleic acid containing SEQ ID NO:5, which is a DNA sequence, also comprises an RNA; and how the DNA comprising cDNA also comprises genomic DNA.

12. Claims 14 and 15 are indefinite because of the use of the term "prokaryotic cell comprises Escherichia coli" or "eukaryotic cell comprises mammalian cell". The term "prokaryotic cell comprises Escherichia coli" or "eukaryotic cell comprises mammalian cell" renders the claim indefinite, it is not clear how a prokaryotic cell or an eukaryotic cell comprise another cell. Use of the term "is" instead of "comprises" is suggested.

13. Claims 17 and 19 are indefinite because of the use of the term "derived from". The term "derived from" renders the claim indefinite, it is not clear what nucleotide sequence the nucleic

acid derived from SEQ ID NO:5 has, and how different the derived nucleic acid is from the parent compound. Use of the term "obtained from" is suggested.

14. Claims 18, 20 and 21 are indefinite because of the use of the term "a kit for detecting the disease related to the mutation of SEQ ID NO. 5 in a mammal or human comprising a probe (or a primer)". The term "a kit for detecting the disease related to the mutation of SEQ ID NO. 5 in a mammal or human comprising a probe (or a primer)" renders the claim indefinite, it is not clear what else is included in the kit besides the probe or the primer; what disease is referred to; and what mutation is referred to, and where the mutation appears in the sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Greenspan *et al.* (GenBank Accession No. M76730, April 27, 1993).

Greenspan *et al.* teach Chinese hamster pro-alpha-1 (V) collagen mRNA (6114 bases) contains nucleotides 2335-2356, which have the same sequence as nucleotides 2702-2723 of SEQ ID NO:5 (See attached sequence match).

16. Claims 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang *et al.* (U. S. Patent 6,569,662, filed July 19, 2000).

Tang *et al.* teach a DNA sequence (SEQ ID NO:282, 2230 bases, Table 2, column 125) encoding a collagen triple helix repeat containing protein contains nucleotides 91-1152, which have the same sequence as nucleotides 1804-2865 of SEQ ID NO:5 (See attached sequence match; claims 17 and 19). Sequence match is obtained with Pub. No. US 2003/0104529 (U. S. Application No. 10/037,270), which is a Division of U. S. Application No. 09/620,312 (U. S. Patent 6,569,662).

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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November 6, 2003